

compounds] Leuprorelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, or Zoladex [and derivatives thereof].

4. **Amended Twice.** A composition [Combined preparation] according to claim 1, [characterised in that the] wherein said one or more LHRH analogues [or the combination of LHRH analogues] is orally bioavailable.

5. **Amended Twice.** A composition [Combined preparation] according to claim 1, [characterized in that the] wherein said one or more LHRH analogues is a non-peptidergic LHRH agonist or non-peptidergic LHRH antagonist.

6. **Amended Twice.** A composition [Combined preparation] according to claim 1, [characterised in that the] wherein anti-[o]estrogen is [selected from the group of compounds] Raloxifen, Droloxifen, or Centohroman [and derivatives thereof].

7. **Amended Twice.** A composition [Combined preparation] according to claim 1, [characterised in that the] wherein said anti-[o]estrogen is [of the] Raloxifen [type].

Rule 126
10
13. **Amended.** A method for treating a gynecological disorder comprising administering one or more [The use of an LHRH analogue or a combination of] LHRH analogues, and [of an] at least one anti-[o]estrogen having tissue-selective [o]estrogenic activity[, for the treatment of gynaecological disorders, especially for the treatment of endometrioses and myomas].

11
14. **Amended.** A method [Use] according to claim 13, wherein said [characterised in that] LHRH analogue and anti-[o]estrogen are administered [simultaneously and/or in chronological sequence] sequentially.

12
15. **Amended.** An article of manufacture [Packaging unit] comprising two spatially separately packaged active ingredients, one of which is at least one [an] LHRH analogue [or a combination of LHRH analogues] and the other of which is an anti-[o]estrogen having

31 cancelled
All claims are not in case

Me
tissue-selective [o]estrogen activity[, and comprising as third component an information leaflet on the simultaneous and/or chronologically sequential administration of the forms of administration].

Please add the following new claims:

16. A composition according to claim 1, wherein said LHRH analogue is an LHRH antagonist.

17. A composition according to claim 1, wherein said LHRH analogue is Leuporelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, or Zoladex and said anti-estrogen is Raloxifen, Droloxifen, or Centchroman.

18. A composition according to claim 1, wherein said anti-estrogen is a selective estrogen-receptor modulator.

19. A method according to claim 13, wherein said gynecological disorder is endometrioses.

20. A method according to claim 13, wherein said gynecological disorder is myomas.

21. A method according to claim 13, wherein said LHRH analogue and said anti-estrogen are administered simultaneously.

22. A method according to claim 14, wherein said anti-estrogen is administered after administration of said LHRH analogue.

23. A method according to claim 13, wherein said LHRH analogue is Leuporelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, Zoladex or combinations thereof and said anti-estrogen is Raloxifen, Droloxifen, Centchroman or combinations thereof.

24. A method according to claim 14, wherein said LHRH analogue is Leuporelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, Zoladex or combinations thereof and said anti-estrogen is Raloxifen, Droloxifen, Centchroman or combinations thereof.

25. A method according to claim 22, wherein said LHRH analogue is Leuporelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, Zoladex or combinations thereof and said anti-estrogen is Raloxifen, Droloxifen, Centchroman or combinations thereof.

26. A method according to claim 13, wherein said LHRH analogue is administered in the amount of 2 µg-20 mg per kilogram of body weight and said anti-estrogen is administered in an amount of 0.1 µg-10 mg per kilogram of body weight.

27. An article of manufacture according to claim 15, further comprising an information leaflet on the simultaneous, sequential or both simultaneous and sequential administration.

28. An article of manufacture according to claim 15, wherein Leuporelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, or Zoladex and said anti-estrogen is Raloxifen, Droloxifen, or Centchroman.

29. An article of manufacturing according to claim 15, wherein said LHRH analogue is peptidergic.

30. A method for ameliorating LHRH analogue-induced reduction in bone density in a patient comprising administering to said patient one or more LHRH analogues and at least one anti-estrogen wherein said one or more LHRH analogues and said at least one anti-estrogen are administered sequentially or simultaneously.

31. A method according to claim 30, wherein said LHRH analogue is Leuporelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂,

B2
contd

Ramorelix, Zoladex or combinations thereof and said anti-estrogen is Raloxifen, Droloxifen, Centchroman or combinations thereof.

32. A method according to claim 30, wherein said anti-estrogen is administered after administration of said LHRH analogue.

33. A method of inhibiting side effects associated with administration of an LHRH analogue comprising administering at least one anti-estrogen and one or more LHRH analogues, wherein administration is sequential or simultaneous.

34. A method according to claim 33, wherein said LHRH analogue is Leuprorelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(Mor)-Pro-D-Ala-NH₂, Ramorelix, Zoladex or combinations thereof and said anti-estrogen is Raloxifen, Droloxifen, Centchroman or combinations thereof.

35. A method according to claim 33, wherein said anti-estrogen is administered after administration of said LHRH analogue.--

REMARKS

Pending Claims

There is some confusion as to the pending claims in the instant application. The application was filed with original claims 1-15. Prior to this Amendment, none of these claims had been canceled.

In a LETTER filed July 28, 1998, applicants provided an English translation of amended page 10 that was attached as an annex to the International Preliminary Examination Report. However, that letter also requested that the examination be based on the original PCT application as filed, not based on amended page claim which only presented claims 1-9.

At the top of page 2 of the July 27, 1999, Office Action, receipt of the Preliminary Amendment is acknowledged. However, the Office Action incorrectly states that only claims 1-9 were presented for prosecution. In fact, original claims 1-15 were presented for prosecution. This is further evidence by the amendments presented in the Preliminary